APPL. NO.: 10/565,346 DOCKET NO.: CPX-015.01

## IN THE CLAIMS

1. (currently amended) A topical foam aerosol formulation comprising

(a) an one or more active agent or agents selected from the group consisting of anti-inflammatory agents, topical anesthetics, topical antibiotics, and anti-fungal agents, and combinations thereof, solubilized or dispersed in an oil and water emulsion, wherein the emulsion does not contain volatile lower alcohols; and the oil phase of the emulsion is 0.8% to 6.0% by weight of the emulsion and is a solid or semi-solid at room temperature; and

- (b) a propellant consisting essentially of a hydrofluoroalkane or a mixture of hydrofluoroalkanes, without additional co-solvents or co-propellants.
- 2. (canceled)
- 3. **(previously presented)** The formulation of claim 1 wherein the active agent is an antiinflammatory agent.
- 4. (previously presented) The formulation of claim 3 wherein the anti-inflammatory agent is selected from the group consisting of alclometasone dipropionate, amcinonide, beclometasone dipropionate, betamethasone benzoate, betamethasone dipropionate, betamethasone valerate, budesonide, clobetasol propionate, clobetasone butyrate, desonide, desoxymethasone, diflorasone diacetate, diflucortolone valerate, flumethasone pivalate, fluclorolone acetonide, fluocinolone acetonide, fluocinonide, fluocortin butyl, fluocortolone, fluprednidene acetate, flurandrenolone, halcinonide, hydrocortisone, hydrocortisone acetate, hydrocortisone butyrate, methylprednisolone acetate, mometasone furoate, triamcinolone acetonide, diclofenac, ibuprofen, acetylsalicylic acid, piroxicam, ketoprofen, felbinac, benzylamine, and combinations thereof.
- 5. **(original)** The formulation of claim 3 wherein the concentration of the antiinflammatory agent is from about 0.01% to 10%.
- 6. (**previously presented**) The formulation of claim 1 wherein the active agent is a topical anesthetic.

AMENDMENT AND RESPONSE

APPL. NO.: 10/565,346 DOCKET NO.: CPX-015.01

- 7. (**previously presented**) The formulation of claim 6 wherein the topical anesthetic is selected from the group consisting of lidocaine, prilocaine, bupivacaine, levobupivacaine, ropivacaine, mepivacaine, procaine, chloroprocaine, propoxycaine, hexylcaine, tetracaine, cyclomethycaine, benoxinate, butacaine, proparacaine, butamben, diperodon, phenacaine, falicaine, dyclonine, pramoxine, dimethisoquin, benzocaine, amethocaine, dibucaine, ketocaine, propanocaine, propipocaine, and combinations thereof.
- 8. **(original)** The formulation of claim 6 wherein the concentration of the anesthetic is from about 1% to about 10%.
- 9. **(previously presented)** The formulation of claim 1 wherein the active agent is an antibiotic or antifungal agent.
- 10. (**previously presented**) The formulation of claim 9 wherein the active agent is an antifungal agent is selected from the group consisting of clotrimazole, econazole, ketoconazole, itraconazole, miconazole, oxiconazole, sulconazole, butenafine, naftifine, terbinafine, undecylenic acid, tolnaftate, nystatin, and sertaconazole nitrate.
- 11. **(original)** The formulation of claim 9 wherein the concentration of the antifungal or antibiotic agent is from about 0.3% to 5%.
- 12. (**currently amended**) A method of making a hydrofluoroalkane containing topical foam formulation free of volatile lower alcohols comprising
  - (a) making an oil in water emulsion with a more than 50% aqueous phase, wherein the oil phase of the emulsion is 0.8% to 6.0% by weight of the emulsion and is a solid or semisolid at room temperature,
  - (b) either dissolving an one or more active agent or agents selected from the group consisting of antiinflammatory agents, topical anesthetics, topical antibiotics, and antifungal agents, and combinations thereof in the aqueous or oil phase prior to emulsification or adding a non-water soluble, non-oil soluble drug to the emulsion to form a dispersion in the emulsion, and

**AMENDMENT AND RESPONSE** 

APPL. NO.: 10/565,346 DOCKET NO.: CPX-015.01

- (c) adding a propellant consisting essentially of a hydrofluoroalkane or a mixture of hydrofluoroalkanes, without additional co-solvents or co-propellants.
- 13. (**previously presented**) A hydrofluoroalkane containing topical foam formulation free of volatile alcohols produced by the method of claim 12.
- 14. **(previously presented)** The formulation of claim 1, wherein the emulsion is about 80% to about 90% (w/w) water.
- 15. (**previously presented**) The formulation of claim 1, wherein the emulsion does not contain ethanol.
- 16. (previously presented) The method of claim 12, wherein the emulsion is about 80% to about 90% (w/w) water.
- 17. **(previously presented)** The method of claim 12, wherein the foam formulation is free of ethanol.
- 18. (**previously presented**) The method of claim 12, wherein adding propellant to the emulsion produces an immediate foaming action on expulsion from a pressurized container.